

## REMARKS

Claims 20-28 have been canceled without prejudice or disclaimer.

Claims 29 and 30 have been added. Claims 29 and 30 are supported by the specification and claims as originally filed, including page 2, line 5 to line 7 and Example 4.

Claims 1, 3, 10 and 15 have been amended. Claim 1 has been amended to include the limitation found in claim 21. Claim 3 has been amended to change its dependency from claim 2 to claim 1. Claim 10 has been amended to change its dependency from claim 10 to claim 1. Claim 15 has been amended to include the limitation found in claim 25. Claim 15 has also been amended to delete the requirement that the protease is derived from a mammal. No new matter has been added and entry of the amendments is respectfully requested.

The specification has been amended to delete the reference to the Danish priority application.

An abstract of the disclosure has been added.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

### I. Priority

The Examiner contends that Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date, alleging that the paragraph at page 5, lines 18-20 of the specification, is not found in the parent application, U.S. Pat. Application no. 09/620,494. In particular, the Examiner concludes that while bovine chymosin was claimed in the parent application, the information regarding commercial availability of preferred sources of enzyme was not provided in the original parent application.

Except for the addition of a cross-reference to the related applications, the present application and the parent application (U.S. Patent Application no. 09/620,494) are identical. Support for the paragraph at page 5, lines 18-20 of the present application is found in the parent application at page 4, lines 16-18.

However, an error in the cross-reference has been identified. Namely, although the present application is a continuation of the parent application, U.S. Patent Application no. 09/620,494, the parent application is now identified as a continuation-in-part (not a continuation) of the original parent, U.S. Patent Application no. 09/358,792 (now U.S. Pat. No. 6,149,950). The

cross-reference to the application is amended herein, and an Application Data Sheet is submitted herewith to correct this error.

## **II. The Specification**

(i) The application is objected to as not containing an abstract. An abstract on a separate sheet is submitted herewith.

(ii) Page 5, line 20 is objected to as having incomplete information, namely, the phrase in referring to the source "Chris Hansen, Inc." Applicants have completed this information by specifying the location of the source company and by correcting the name of the source company, i.e., from "Chris Hansen, Inc." to "Chr-Hansen A/S." The completion of this information is clearly not new matter, as it merely identifies the geographic location of the source and provides the formal company name.

(ii) Claim 10 is objected to as improperly depending from itself. Claim 1 has been amended to depend from claim 1.

Applicants respectfully request reconsideration and withdrawal of these objections.

## **III. The Rejection of Claims 21-28 under 35 U.S.C. 112**

a. Claims 21-28 are rejected under 35 U.S.C. 112, as allegedly indefinite on the basis that the phrase "defined as" is vague and confusing.

Claims 21-28 have been canceled. Reconsideration and withdrawal of the rejection is respectfully requested.

b. Claims 21-28 are rejected under 35 U.S.C. 112, as allegedly indefinite on the basis that the phrase "only one of two of the major protein components of meat" is indefinite. The Examiner states that it is unclear where the specification provides support for this phrase. The Examiner also alleges that this phrase is indefinite because the specification states the enzymes digest "either or both," and that one skilled in the art would not recognize which protein applicant is referring refers, in order to select an enzyme encompassed by the claims.

Claims 21 and 28 have been canceled. The limitation of claim 21, however, has been incorporated into claim 1, and the limitation of claim 25 has been incorporated into claim 15. In

this regard, the phrase “only one of two of the major protein components of meat” is clearly supported by the specification at page 2, line 5 to line 7. In order to expedite prosecution, the claims have been amended to recite the exact phrase (i.e., word for word) used in the specification, namely, that it is digestion of “only one of the two major protein components of meat.”

Applicants respectfully disagree with the Examiner’s allegations that one skilled in the art would not recognize which protein Applicant is referring to by this phrase. As is well known in the art, and as clearly recited in the specification on page 1, the two major proteins of meat are collagen and the myofibrillar proteins. Given that there are only two major proteins, an artisan would clearly recognize that the phrase “digest only one of the two major protein components of meat” clearly means that the enzyme digest (a) collagen, but not the myofibrillar proteins or (b) myofibrillar proteins, but not collagen. Thus, the phrase “digest only one of the two major protein components of meat” is clearly not indefinite.

c. Claims 21-28 are rejected under 35 U.S.C. 112, as allegedly indefinite on the basis that the phrase “two of the major protein components of meat” is not defined by the claims or the specification. As is well known in the art, and as clearly recited in the specification on page 1, the two major proteins of meat are collagen and the myofibrillar proteins. Further support is also provided in Example 4, discussing the measurement of hydrolytic potential of a protease for the two major protein components of meat.

d. Claims 21-28 are rejected under 35 U.S.C. 112, as allegedly indefinite on the basis that because myofibrillar proteins are composed of the three proteins (myosin, actin and tropomyosin), it is unclear if the enzyme activity is to act on any or all of the subsets.

Applicants respectfully submit that, in the case, where the one of the two major protein components of meat is the myofibrillar protein, that the enzyme must simply have activity on at least one of the myofibrillar proteins. Thus, the claims are not indefinite.

e. Claims 22-24 and 26-28 are rejected as indefinite for the recitation of the degree of hydrolysis as “definition” of an enzyme’s specificity is not appropriate.

Claims 22-24 and 26-28 are canceled. Applicants respectfully request reconsideration and withdrawal of the rejection.

f. Claims 25-28 are rejected as indefinite for the recitation of "the method of claim 15" since claim 15 is a composition claim.

Claims 25-28 are canceled. Reconsideration and withdrawal of the rejection is respectfully requested.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **IV. The Rejection of Claims 1, 10, 13 and 21-24 under 35 U.S.C. 102 over Paulin**

Claims 1, 10, 13, and 21-24 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by Paulin (EP 0 362 177). The Examiner alleges that Paulin teaches the use of "heat sensitive enzyme", that is, a fungal thermolabile protease, in a method of tenderizing and processing meats. The Examiner alleges that this protease is known in the art as having "limited substrate specificity" on aspartic endopeptidase. The Examiner also alleges that the meat and enzyme are mixed and then filled into tins, thus reading upon the "tumbling" of claim 10. With respect to the degree of hydrolysis, the Examiner alleges that the claims do not state that the meat proteins are digested, rather that limited substrate specificity is defined as digestion to a particular degree of hydrolysis. The Examiner states that absent clear and convincing evidence or arguments to the contrary, it is asserted that the enzyme of Paulin also teaches the degree of hydrolysis recited in claims 21-24. This rejection is respectfully traversed.

Paulin clearly does not anticipate the claimed invention. Paulin does not, as alleged by the Examiner, disclose, or even suggest, a method of tenderizing meat. Paulin is directed to a method for improving the properties of a forcemeat product. Forcemeat, however, is a processed (emulsified) meat product, such as, e.g., sausage, luncheon meat, pates and patties. See, e.g., Paulin at page 4, lines 25-26 and at page 1, lines 6-9 (describing how forcemeat is prepared). Forcemeat is not an intact meat, and a method of tenderizing is simply not relevant for such meat products, which are ground or otherwise processed. In this regard, the purpose for which Paulin is using the heat sensitive enzyme containing material on processed meat, such as, sausage (e.g., improved flavor) is completely remote from a method for tenderizing meat, as required by the present claims. Therefore, Paulin does not teach a method for tenderizing meat, nor is a method for tendering meat inherent in the Paulin process.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

**V. The Rejection of Claims 1, 3-15, 17-19 and 21-28 under 35 U.S.C. 102 over Wistreich**

Claims 1, 3-15, 17-19 and 21-28 are rejected under 35 U.S.C. 102(b) over Wistreich et al. (U.S. Pat. No. 3,399,065). The Examiner alleges that Wistreich et al. disclose a method of producing sausages by adding both a powdered milk and powdered enzyme capable of precipitating proteins when both are in an aqueous medium. The Examiner alleges that Wistreich et al. teach that the milk solids and enzyme may be added separately or as a premixed composition and that preferred enzymes are rennin, pepsin, trypsin, papain, bromelin, ficin and the like. The Examiner contends that because the claims "comprise" certain steps and ingredients, they read upon the method and compositions disclosed in Wistreich et al. As an example, the Examiner states that the claims do not exclude the use of milk solids in addition to protease. This rejection is respectfully traversed.

The anticipation rejection over Wistreich et al. is also clearly improper. Like Paulin, Wistreich et al. is directed to a method for producing sausage-type products, which is a ground or processed meat product. See Wistreich et al. at col. 1, line 31-34. As discussed with regard to the rejection over Paulin, a method for tenderizing meat is not relevant to the production of ground or processed meat products such as, a sausage. Indeed, the purpose of the enzyme treatment process of Wistreich et al. is to improve the moisture of the product, not to tenderize the meat. See Wistreich at col. 1, lines 60-68.

Applicants also disagree with the Examiner conclusions that the use of the phrase "comprises" opens the present claims to reading on Wistreich et al., since the claims do not exclude the use of milk proteins. As clearly disclosed in col. 2, lines 10-19, the Wistreich et al. invention is

based upon the discovery that proteins of milk, often when precipitated referred to as casein, precipitated in situ in ground meat by enzymatic action as the temperature of the mixture rises, impart enhanced water absorbing properties which are maintained ever upon being subject to elevated temperature during and after cooking.

The use of enzymes to modify milk proteins for use in improving the water retention of a ground meat product does not teach or even suggest a method for tendering meat. Thus, the fact that the claims (by using the open-ended transitional phrase comprising) do not exclude ingredients required in Wistreich et al. is an irrelevant point because Wistreich et al. does not otherwise teach or suggest the elements of the claimed invention.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VI. The Rejection of Claims 1, 3-4, 7-14 and 21-24 under 35 U.S.C. 102(b) or alternatively under 35 U.S.C. 103(a) Over Robbins et al.**

Claims 1, 3-4, 7-14 and 21-24 are rejected under 35 U.S.C. 102(b) or alternatively under 35 U.S.C. 103 as being unpatentable over Robbins et al. The Examiner alleges that Robbins et al. teach a method for tendering meat with an aspartic acid protease from *Trichoderma reesei*, that acts selectively upon the myofibrillar proteins of meat producing a uniform texture. This rejection is respectfully traversed.

Robbins et al. does not teach a protease which has the limited substrate specificity recited in the claims, namely, the digestion of only one of the two major protein components of meat.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VII. The Rejection of Claims 3-9, 11-12, 14-19 and 21-28 under 35 U.S.C. 103**

Claims 3-9, 11-12, 14-19 and 21-28 are rejected under 35 U.S.C. 103 as being unpatentable over Paulin in view of Wistreich et al., as evidenced by Bender et al. This rejection is respectfully traversed.

As previously discussed, Paulin and Wistreich et al. clearly do not teach the claimed invention, as among other things, they are directed to a method for producing sausage-type products, which is a ground or processed meat product. The addition of Bender et al. for teaching the use of rennet does not correct the deficiencies of Paulin and Wistreich et al.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

**VIII. Double Patenting**

Claims 1, 10, 13 and 21-24 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-22 of U.S. Patent No. 6,149,950.

A terminal disclaimer over this patent is submitted herewith. Applicants respectfully request reconsideration and withdrawal of the rejection.

**IX. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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## ABSTRACT

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The present invention relates to methods for tenderizing meat comprising contacting meat with a tenderizing-effective amount of a thermolabile protease having limited substrate specificity, wherein the limited substrate specificity is the digestion of only one of the two major protein components of meat.